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IN THE

Supreme Court of the United States

OCTOBER TERM, 1980

MARK MILLS, *et al.*, *Petitioners*,

v.

RUBIE ROGERS, *et al.*, *Respondents*.

On Writ Of Certiorari To The United States Court Of Appeals For The First Circuit

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BRIEF FOR THE AMERICAN COLLEGE OF NEUROPSYCHOPHARMACOLOGY AS AMICUS CURIAE

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QUESTIONS PRESENTED

1. Does an involuntarily committed psychiatric patient have a federal constitutional right to refuse the administration of antipsychotic medication?

2. If the Due Process Clause of the Fourteenth Amendment requires inclusion of procedural safeguards prior to the nonconsensual administration of antipsychotic medication, what accommodation should be achieved between the rights of the patient and the duties of the state?

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BRIEF FOR THE AMERICAN COLLEGE OF NEUROPSYCHOPHARMACOLOGY AS AMICUS CURIAE

INTEREST OF AMICUS CURIAE

The American College of Neuropsychopharmacology (ACNP) is a non-profit, tax-exempt, scientific professional organization whose members are drawn from the fields of psychiatry, psychology, pharmacology, neurophysiology, neurochemistry, biochemistry and internal medicine. Its members are selected for membership to ACNP by their peers primarily on the basis of their original scholarly contributions to the field of neuropsychopharmacology, which involves the evaluation of the effects of synthetic

compounds or natural products upon the brain and human behavior. Among the 420 members of ACNP are governmental officials with the United States Department of Health and Human Services, chairmen of academic departments, directors of state psychiatric research facilities, and directors of research at private pharmaceutical companies.

A primary function of ACNP is to serve as a forum for the exchange of scientific information regarding the pharmacology, toxicology and clinical application of neuropsychopharmacological agents. ACNP members have testified as expert witnesses in the trial of this and other major cases; have worked jointly with various administrative agencies and executive departments; and have testified before Congress on numerous legal, ethical, and scientific issues relating to neuropsychopharmacology and national health policy. Many of the federal government's expert advisers on the use of antipsychotic and neurological substances, and their potential for abuse, are members of the ACNP.

ACNP seeks to have the dramatically beneficial contribution of psychopharmacology to modern psychiatric treatment in the second half of the Twentieth Century recognized by the Court in any resolution of the current controversy. In order to protect the therapeutic treatment advances already made, antipsychotic drug therapy must exist within a legal framework that is adapted to the contemporary needs of public psychiatric care. An appropriate resolution of the legal issues also will allow the future development of chemotherapeutic treatment of psychiatric disorders.

Amicus has secured the consent of the parties to the filing of its *amicus curiae* brief. The consenting letters are being filed simultaneously with delivery of the brief to the Clerk of this Court.

STATEMENT OF THE CASE

Respondents are psychiatric patients at Boston State Hospital, a Massachusetts commonwealth psychiatric treatment facility. They alleged, in a class action brought under 42 U.S.C. §1983, that they were being deprived of various constitutional rights. As relief, they sought to enjoin certain seclusion and medication practices at the institution and to recover damages from those responsible for such practices.

On October 29, 1979, the District Court issued an order and judgment which granted injunctive relief to the class on both the medication and seclusion claims while denying the damage claims. In pertinent part, the injunction provided that state hospital employees were restrained from forcibly medicating patients at Boston State Hospital without the patient's consent (or the consent of the patient's guardian) except in an emergency situation defined as "a substantial likelihood of, or as a result of, extreme violence, personal injury or attempted suicide. . . ." Order and Judgment, Pet. App. 163a.

The defendants (petitioners) noted an appeal to the Court of Appeals for the First Circuit from that portion of the court's order enjoining the forcible use of antipsychotic medication in nonemergency situations. The plaintiffs (respondents) cross-appealed on the denial of damages.

On November 25, 1980, the First Circuit affirmed in part, reversed in part, vacated the order of the trial court and remanded the case. The First Circuit affirmed the ruling that antipsychotic medications could not be forcibly administered to an involuntarily committed mental patient solely for treatment purposes in nonemergency situations, absent an adjudicative finding of incompetency. The Circuit Court rejected, however,

the District Court's definition of "emergency." It expanded the situations where medication could be forcibly employed absent a declaration of incompetency to include where: (1) a treating psychiatrist determines that the medication is necessary to prevent violence, or (2) a delay could result in significant deterioration in the parient's mental health. The First Circuit determined that a balance recognizing the facts of each situation had to be drawn between the interests of the patient and those of the state. The case was then remanded to the District Court with the instruction that the court "be creative in designing procedural mechanisms" to enforce a mental patient's right to refuse treatment.

On remand, the District Court declared at a status conference that its original order regarding emergency medication stood intact. Pet. App. 176a. That statement by the District Court led petitioners to seek clarification from the First Circuit. The First Circuit declined to clarify further its opinion until the trial court had acted more formally on the remand. At that time, petitioners sought a writ of certiorari from this Court under the Court of Appeal's decision only as it related to involuntarily committed patients. Certiorari was granted on April 20, 1981.

SUMMARY OF ARGUMENT

Psychotherapeutic drugs have played a major role in permitting outpatient treatment of individuals with mental disorders who previously had to be institutionalized. Drug therapy also has raised the level of psychiatric treatment available in public institutions. The unique characteristics of antipsychotic medication give rise to a significant issue concerning their mandated use for diagnosible mental illness. In many instances, the failure to use antipsychotic drugs would amount to psychiatric

malpractice. Whether the state is even permitted under the state's police power or as *parens patriae* to deliver medically appropriate care over a psychotic patient's objections is judicially unsettled.

The patient has an interest in minimizing governmental interference with his right to liberty, especially with respect to the long-term use of medication with potentially harmful side effects. This right is not absolute. It must be balanced against both the societal and individual interest in the provision of efficacious medical treatment and the societal need to protect the safety of other patients, the institutional staff, and the community. Any judicially sanctioned procedure should recognize the often diminished or altered mental state of the patient who is asserting the existence of a right to avoid potentially helpful treatment. Given the particular medical context of this conflict, amicus submits that adversarial competency and guardianship proceedings, as required by the decision of the lower court, are neither constitutionally necessary, nor appropriate for protection of the asserted rights.

The vast majority of patients committed to an institution, especially a state-run facility, need some form of drug therapy and also need review of the quality of the treatment which they are receiving. The Due Process Clause of the Fourteenth Amendment requires a treatment initiation hearing and periodic treatment review of non-emergency, involuntary medication of committed psychiatric patients. While in some situations it may be appropriate for the committing court to consider the issue of medication for a patient, in the majority of circumstances the optimal procedure for a state to adopt in determining the appropriateness of nonemergency medication would be an administrative treatment review board having as a member an independent psychiatrist with an expertise in psychopharmacology.

ARGUMENT

I. AN INVOLUNTARILY HOSPITALIZED PSYCHIATRIC PATIENT HAS A QUALIFIED FEDERAL CONSTITUTIONAL RIGHT TO A REVIEW OF THE NONCONSENSUAL ADMINISTRATION OF ANTIPSYCHOTIC MEDICATION.

Any constitutional right which a committed patient at a psychiatric treatment facility has with respect to the administration of antipsychotic medicine should be consonant with the necessary role that such medication plays in current treatment of patients with psychotic disorders.

A. Antipsychotic Medication Is A Necessary, Effective And Relatively Safe Treatment Modality For A Wide Range Of Psychotic Disorders.

The contemporary use of antipsychotic drugs in psychiatric institutions has had a dramatic and beneficial effect upon the nature and quality of treatment which the state may offer to mentally ill patients confined to its care.

1. Pre-1950 care of state mental patients

Public treatment of the mentally ill may be meaningfully divided into four historical periods: (1) pre-19th century neglect, (2) 19th century creation of state mental hospitals modeled after the treatment philosophies of Vincenzo Chiarugi, Philippe Pinel and others, (3) early 20th century custodial mental health hospitals and (4) pharmacological treatment and community mental health care begun after 1950.[1] O. Ray, Drugs, Society and

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[1] *See also* D. F. Klein, R. Gittelman, F. Quitkin and A. Rifkin, Diagnosis and Drug Treatment of Psychiatric Disorders: Adults and Children xxix-xxx (2d ed. 1980); S. Rep. No. 712, 96th Cong., 2d Sess. 7-12, *reprinted in* [1980] U.S. Code Cong. & Ad. News 3375-3377, *citing* Greunberg and Archer, *Abandonment of Responsibility for the Seriously Mentally Ill*, 57 Health & Society 485

Human Behavior 245-248 (1978). *See generally Parham* v. *J. R.*, 442 U.S. 584, 598-99 (1979); *O'Connor* v. *Donaldson*, 422 U.S. 563, 582-84 (1975) (Burger, C.J., concurring).

Prior to the 19th Century, the mentally ill either were largely neglected and left to wander idly in the streets or were kept in locked quarters at home or in jail with chain restraints and without the benefit of medical attention. J. Schneck, *United States*, in World History of Psychiatry 432 (J. Howells, ed. 1975); Ray, *supra*, at 246. The reform movement began in Florence, Italy, under Dr. Vincenzo Chiarugi at the Hospital Bonifacio, and in Paris, France, with Dr. Philippe Pinel transforming care of the mentally ill at two hospitals, the Bicetre and the Salpetriere, through "moral treatment."[2] F. G. Alexander and S. T. Selesnick, The History of Psychiatry 112-118 (1966); G. Mora, *Historical and Theoretical Trends in Psychiatry*, in 1 Comprehensive Textbook In Psychiatry-II 1, 42-45 (2d ed. Freedman, Kaplan, & Sadock 1975). *See also* Senate Report, *supra* note 1, at 3375. Simultaneously, in England, a group of Quakers led by William Tuke founded the York Retreat offering a similar type of care. *Id.*

In the United States during the early nineteenth century, a number of physicians[3] and social reformers suc-

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(Milbank Memorial Fund, 1979)(cited subsequently as Senate Report, *as found in*, [1980] U.S. Code Cong & Ad. News).

[2] The objective of moral treatment was to serve the personal needs of psychotic patients and to elicit dormant faculties for self care through calm, respectful treatment. Ray, *supra* at 246; Senate Report, *supra* note 1, at 3375.

[3] Benjamin Rush, a signatory of the Declaration of Independence, is regarded as the "Father of American Psychiatry." Schneck, *supra*, at 433; Alexander and Selesnick, *supra*, at 120-121. In addition to a humanistic approach to patients suffering from mental disorders, his treatment regimen unfortunately included restraints and blood letting. *Id.* Therefore, the first American physicians credited

ceeded in establishing hospitals such as the Hartford Retreat and the McLean Hospital which were fashioned upon the European models.[4] Senate Report, *supra*, at 3376. Dorthea Dix, Horace Mann and Charles Sumner urged the states to assume financial responsibility for the treatment of the mentally ill and to establish small hospitals in rural areas offering a therapeutic approach. *Id.* The results were immediately felt. Discharge rates, a valid measure of success, increased dramatically.[5] *See* Ray, *supra*, at 246; Bockoven, *supra* note 4, at 14-15.

The popularity of the mental health reform programs also led to an expanded state hospital population in the late 19th Century. Conditions eventually reached the point where treating personnel were grossly overloaded, yielding an increasing backlog of cases. As a result, treatment appeared to become less successful.[6] Senate

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with applying the moral treatment method in America include John Butler, Isaac Ray, Eli Todd and Samuel B.Woodward. *Id.*

[4] Moral treatment was undertaken principally at private, corporate hospitals. It was applied to relatively small numbers of patients at each hospital. Almost all of the patients were from homogeneous New England middle-class or upper-class backgrounds. G. Mora, *supra*, at 49. *See* J. Bockoven, Moral Treatment in Community Mental Health 38 (1972); R. Caplan, in collaboration with G. Caplan, Psychiatry and the Community in Nineteenth Century America 89 (1969); G. Grob, *Samuel B. Woodward and the Practice of Psychiatry in Early 19th Century America* 36 Bull. History Medicine, 420-433 (1962).

[5] Even the writer Charles Dickens, who was generally unimpressed with the United States, favorably viewed the humane treatment given mental patients at the Boston Lunatic Asylum after a visit there. C. Dickens, I American Notes 105 (1842).

[6] Historians assert that a major factor in the decline of moral treatment was the unanticipated influx of patients from diverse economic, religious and ethnic backgrounds into the hospitals and the diversion of criminals, alcoholics and vagrants from jails to

Report, *supra*, at 3376. Predictably, the confidence of the staff in mental hospitals as well as of the public in the ability of society to successfully treat the mentally and emotionally disturbed declined. R. Caplan, *supra* note 4, at 89.

As late as 1961, the Joint Commission on Mental Illness and Health, created by the Health Study Act, Pub. L. No. 84-182, §304(b) 69 Stat. 381, 383 (1955), noted that half of the patients in state psychiatric hospitals received no active treatment of any kind designed to improve their mental condition, and that most of the patients in continued treatment wards were receiving no treatment at all. H. Schulberg and F. Baker, The Mental Hospital and Human Services 21 (1975). *See also* Senate Report, *supra*, at 3379. Prior to 1955, progressive medical treatment of psychiatric disorders (beyond mere custodial care and physical restraints) meant the use of barbiturates, bromides, narcotics and anticholinergic drugs for sedation, soothing baths, wet packs, shock therapy with insulin, atropine or convulsant drugs and subsequently, electrically induced convulsions and neurosurgical techniques including prefrontal leucotomy. R. Baldessarini, Chemotherapy in Psychiatry 2-3 (1977); Klein, *et al.*, *supra* note 1, at xxix.

2. Post-1950 impact of psychopharmacology on the treatment of psychiatric disorders

In 1952, the first antipsychotic drug,[7] chlorpromazine, was synthesized as the byproduct of meticulous

mental hospitals. *See, e.g.*, Mora, *supra*, at 52; Schneck, *supra*, at 446; H. Schulberg and F. Baker, The Mental Hospital and Human Services 18 (1975).

[7] The term "antipsychotic" is used in both a narrow sense and a broad sense. In its narrow sense, it refers to the classes of drugs (phenothiazines, butyrophenones, thioxanthenes, reserpine and other miscellaneous antipsychotic agents) which have proven to be ef-

laboratory research into the antihistaminic effects of phenothiazines. The discovery during the 1950's of antipsychotic and other psychotropic drugs[8] useful in treating each of the major psychoses (severe depression, mania and schizophrenia) dramatically altered the practice of psychiatry. Alexander and Selesnick, *supra*, at

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ficacious in the treatment of patients suffering from schizophrenia. *See* D. Greenblatt and R. Shader, *Psychotropic Drugs in the General Hospital*, in Manual of Psychiatric Therapeutics 11-14 (R. Shader ed. 1975). Such drugs are marketed under trade names which include Thorazine, Prolixin, Mellaril, Haldol and Trilafon. These substances are described also as "major tranquilizers" or "neuroleptic" drugs, although these descriptions have been subject to criticism. *See* Klein, *et al.*, *supra*, at 41; Baldessarini, *supra*, at 12.

In its larger sense the term antipsychotic drug is inclusive of other psychotropic drugs which treat the major psychoses such as antidepressant drugs (tricyclics and monoamine oxidase inhibitors) and the antimania drug lithium. Lower courts have noted that many psychiatrists use the term antipsychotic in its broader sense as interchangable with the term psychotropic. *See, e.g., Rogers* v. *Okin*, 634 F.2d 650, 653 n.1 (1st Cir. 1980); *In the Matter of Guardianship of Richard Roe III*, Mass. Adv. Sh. 981, 1003, n.10 (1981). Although the lower courts have used "antipsychotic" in its more narrow sense, amicus contends that any determination of the legal status of the administration of antipsychotic medication should refer to the broader use of the term; otherwise, confusion is likely to cloud any use of psychotropic drugs by treating physicians.

[8] Most of the available psychopharmaceutical drugs were developed in one of three ways: rediscovering and exploiting a folk usage of a natural product (reserpine, opioids, amphetamines); serendipitious or accidental observation that an agent developed for another purpose has a desirable but unexpected clinical effect (chlorpromazine, iproniazid, imipramine, meprobamate); or synthesizing and screening structural analogues of known products or entirely novel compounds (piperazine phenothiazines, thioxanthenes and butyrophenones). Baldessarini, *supra*, at 4-5. *See also* Discoveries in Biological Psychiatry (F. Ayd and B. Blackwell ed. 1970) for a historical retrospective on the development of each of the major psychotropic drugs by the scientists who discovered them.

289. The effect of psychotropic drugs on psychiatry during the last twenty-five years has been compared to the impact of antibiotics on the general practice of medicine. Baldessarini, *supra*, at 2.

Even though the number of admissions to state hospitals increased from 1946 to 1976, the resident population dramatically decreased from 558,900 patients in 1955 to 170,700 patients in 1976. Ray, *supra*, at 251. *See also, Jackson* v. *Indiana*, 406 U.S. 715, 737 n.22 (1972). In conjunction with the effort to develop community mental health facilities, psychotropic drugs played a major factor in this declining institutionalized mental health population in the U.S.[9] Ray, *supra*, at 251.

Lower federal courts which have taken testimony regarding effects of antipsychotic drugs have concluded that they are an effective method of reducing thought disorders in a majority of schizophrenic patients and are often required in order for some patients to participate and derive benefit from other forms of therapy.[10] *See*

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[9] For the role of the community mental health center movement, *see* Senate Report, *supra*, at 3377-94; H. Schulberg and F. Baker, *supra*, at 23 ff.

[10] The District Court employed the term "mind-altering" to describe the reduction in thought disorder which normally accompanies the administration of antipsychotic medication. *Rogers* v. *Okin*, 478 F. Supp. 1342, 1360 (D. Mass. 1979), *aff'd in part, rev'd in part, and remanded*, 634 F.2d 650 (1st Cir. 1980), *cert. granted*, No. 80-1417 (April 20, 1981). Amicus suggests that the term "mind-altering" carries an unfortunate pejorative connotation which may demean the positive aspects of these drugs. Psychotic disease alters the minds of afflicted patients; antipsychotic medication is mind restorative. While it is conceivable that antipsychotic drugs could be overprescribed in an abusive manner so as to "quiet" a patient, their proper use is to diminish disturbances in thinking (such as delusional beliefs) without altering the essential character or per-

Davis v. *Hubbard*, 506 F.Supp. 915, 927 (N.D. Ohio 1980); *Rone* v. *Fireman*, 473 F.Supp. 92, 108 (N.D. Ohio 1979); *Rennie* v. *Klein*, 462 F.Supp 1131, 1137 (D.N.J. 1978), *supplemented and expanded to entire patient class*, 476 F.Supp. 1294, *appeals heard en banc*, Nos. 79-2576, 2577 (3d Cir. May, 1981). Psychotropic drugs are widely accepted in present psychiatric practice as the treatment of choice for mental and emotional disturbances such as schizophrenia. *Rone* v. *Fireman*, 473 F.Supp at 108; *Rennie* v. *Klein*, 462 F.Supp at 1137. The District Court in this case recognized that most of the named plaintiffs showed eventual improvement as a result of the medication and that the use of antipsychotic medication was not inconsistent with accepted medical standards. *Rogers* v. *Okin*, 478 F.Supp. at 1386.

The medical efficacy of chlorpromazine and other antipsychotic drugs has been studied in hundreds of double blind studies.[11] J.M. Davis and J.O. Cole, *Anti-*

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sonality of a patient. L. Lasagna, *The Boston State Hospital Case (Rogers* v. *Okin*): *A Legal, Ethical and Medical Morass*, 25 Journal of Perspectives in Biology and Medicine __ (unpublished text at 25).

[11] Although the concept of blind control clinical trials was known and used by scientists prior to its application in psychopharmacology, more sophisticated techniques were developed for the testing of antipsychotic medication in order to properly evaluate the drugs and to overcome the prevailing level of scepticism among most psychiatrists at the time regarding biochemical treatment of psychiatric disorders. L. Hollister, *Psychopharmacology in its Second Generation*, 141 Military Medicine 371, 372 (1976); Ray, *supra*, at 253.

In 1962, Congress amended the Federal Food Drug and Cosmetic Act to require "evidence consisting of adequate and well-controlled investigations" in drug company applications for approval of new drugs. 21 U.S.C. § 355(d) (1981). *See Weinberger* v. *Hynson, Wescott and Dunning, Inc.*, 412 U.S. 609, 617 (1973). Placebo control is one of the approved methods of "blinding" to ensure quantitative verification of efficacy. 21 C.F.R. § 314.111(a)(5)(ii)(a)(4)(ii) (1980).

psychotic Drugs, in 2 Comprehensive Textbook of Psychiatry-II 1921, 1922. In the vast majority of these studies, antipsychotics proved superior to placebos in the treatment of acute and chronic schizophrenic patients. *Id.* Antipsychotics are easily absorbed within the body, have no addictive effects and are much less likely to have the gross intoxicating effects found in classic sedative agents.[12] Baldessarini, *supra,* at 22-25.

3. The risk of tardive dyskinesia

The principal risk connected with the use of antipsychotic drugs cited by the District Court and by the Circuit Court of Appeals is the potential side effect of tardive dyskinesia. *Rogers* v. *Okin* 478 F.Supp. at 1360, *modified,* 634 F.2d at 653 n.1. Tardive dyskinesia is a neurological syndrome consisting primarily of abnormal motor movements of the face. Klein, *et al., supra,* at 181.

As early as 1973, the ACNP, in connection with the Food and Drug Administration (FDA), alerted the medical community to the symptoms of this side effect. *See* ACNP-FDA Task Force, *Neurologic Syndromes Associated with Antipsychotic-Drug Use,* 289 New England

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[12] Many psychopharmacologists contend that the techniques of the science are now moving into a second generation. *See, e.g.,* Hollister, *supra* note 11; *Joint Hearings* on *Pharmaceutical Research Before the House Comm. on Science and Technology, Subcomm. on Natural Resources, Agriculture Research and Environment* and *Subcomm. on Investigations and Oversight,* 97th Cong. 1st Sess. (April 21, 1981)(Statements of F. Goodwin & F. Bloom). It now appears possible due to increased knowledge about nerve transmission that psychopharmacological investigators will be able to make compounds which are very similar to natural chemical substances of the brain which may be "abnormal" in people with some mental illness. Though the use of nuclear medicine and other advanced research techniques, researchers hope to develop natural substances to treat psychiatric illness without the drawbacks of current medicines. *Id.*.

Journal of Medicine 20 (1973). At that time, FDA and ACNP jointly recognized that "[b]ecause of the lack of adequate substitutes for antipsychotic drugs in the treatment of psychosis, tardive dyskinesia has been accepted as an undesirable but occasionally unavoidable price to be paid for the benefit of prolonging antipsychotic drug therapy." *Id.* at 23. That report suggested that the risk of tardive dyskinesia could be reduced by: (1) minimization of the use of medication in long-term patients, (2) discontinuance or reduction of dose at the first sign of abnormal oral movements, and (3) careful observation of elderly patients. *Id.*

One recent study summarizing literature on the syndrome concluded that despite the risk of the development of tardive dyskinesia it would be a clinical error to deny a schizophrenic patient an antipsychotic drug. D. Jeste and R. Wyatt, *Changing Epidemiology of Tardive Dyskinesia: An Overview,* 138 Am. J. Psychiatry 297, 306 (1978). Patients are committed to treatment facilities under a physician's care for proper care and treatment; antipsychotic drugs are the single best available treatment for schizophrenia. *Id.* at 307.

Thus, psychopharmacologists, psychiatrists and other physicians treating psychotic behavior have been repeatedly informed of the risk that tardive dyskinesia poses to their patients and in practice seek to lessen any drastic adverse effects of antipsychotic drugs. However, considered medical judgment still supports the use of antipsychotic drugs, where they are properly administered and monitored, because they are more than helpful; they are necessary, effective and relatively safe in the treatment of psychotic disorders.

B. Although Lower Federal Courts Have Prohibited Certain Types of Forced Psychiatric Treatment On Constitutional Grounds, The Type of Treatment Which May, If Necessary, Be Forcibly Administered To Involuntarily Committed Patients Needs Clarification.

The power of the state to regulate and maintain the general welfare of its people sometimes limits the individual's right to liberty. *Jacobson* v. *Massachusetts,* 197 U.S. 11, 26-27 (1905). Even though this Court has never directly specified when a civil commitment for mental illness would be authorized, it has recognized that these grounds often include danger to the patient, danger to others or the need for care, treatment or training. *See Jackson* v. *Indiana,* 406 U.S. at 736-37.

Beyond protecting the public safety through its police power, the state also acts as *parens patriae* for all of its citizens. *See Hawaii* v. *Standard Oil Company of California,* 405 U.S. 251 (1972). The state has a legitimate interest under its *parens patriae* power in providing care to those of its citizens who, because of emotional disorders, are unable to care for themselves. *Addington* v. *Texas,* 441 U.S. 418, 426 (1979).

Commitment to a mental institution necessarily entails a "massive curtailment of liberty." *Humphrey* v. *Cady,* 405 U.S. 504, 509 (1972). It is a denial of liberty to which due process standards apply.[11] *Parham* v. *J.R.,* 442 U.S. 584, 600 (1979); *Addington* v. *Texas,* 441 U.S. at 425. Due process further requires that if the state is to deny the liberty of an individual who does not pose a threat to himself or others, there comes a time when it must either attempt to treat that person or release him. *See O'Connor* v. *Donaldson,* 422 U.S. 563 (1975). While in

[11] Even the involuntary transfer of a prisoner to a mental institution has stigmatizing consequences which trigger due process protections. *Vitek* v. *Jones,* 445 U.S. 480, 492-93 (1980).

numerous psychiatric patient class action suits lower federal courts have continued to delineate a constitutionally protected "right to treatment," and, on the legal basis of the putative right to treatment, have required massive changes in the deplorable conditions and lack of treatment found at many state psychiatric facilities, this Court has not decided whether any constitutional right to treatment exists.[14]

A patient's right to treatment, however delineated, and the corollary duty of a physician to employ proper medical judgment are vital factors reflected in this case which are complicated by the characteristics of the drugs at issue and the patients for whom they are prescribed. Amicus contends that the commitment of a patient to a state psychiatric facility includes an implicit prescription for active treatment rather than mere custodial care. Proper medical treatment of psychotic patients has come to necessarily include the use of antipsychotic drugs since these drugs are generally recognized as the most suitable therapy.

While the existence of involuntary commitment statutes suggests that medical treatment must be available to the patient, whether a specific, and ap-

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[14] *See, e.g., Davis* v. *Hubbard,* 506 F.Supp. 915, 921 (N.D. Ohio 1980); *Eckerhart* v. *Hensley,* 475 F.Supp. 908, 913-916 (W.D. Mo. 1979); *Johnson* v. *Solomon,* 484 F.Supp. 278, 298-300, (D. Md. 1979); *Gary W.* v. *State of La.,* 437 F.Supp. 1209, 1222-1223 (E.D. La. 1976). These cases rely heavily on pre-*O'Connor* precedent such as *Wyatt* v. *Stickney,* 325 F.Supp. 781 (1971), *aff'd sub nom. in part, rev'd in part, and remanded on other grounds, Wyatt* v. *Aderholt,* 503 F.2d 1305 (5th Cir. 1974); *Rouse* v. *Cameron,* 125 U.S. App. D.C. 366, 373 F.2d 451(1966); *Welsch* v. *Likins,* 373 F.Supp. 487 (D. Minn. 1974).

Amicus recognizes that in this Court's consideration of *Romeo* v. *Youngberg,* 644 F.2d 147 (3d Cir. 1980), *cert. granted, Youngberg* v. *Romeo,* No. 80-1429 (May 18, 1981) this issue may be addressed.

parently necessary, treatment should then be compelled is another issue. L. Roth, *Involuntary Civil Commitment: The Right to Treatment and the Right to Refuse Treatment,* in Psychiatrists and the Legal Process: Diagnosis and Debate 332, 334 (R. Bonnie ed. 1977).

Constitutional and state statutory proscriptions have developed relating to the type of treatment which may be given to mental patients and prisoners. It is clear that the involuntarily committed patient or prisoner status is not the legal equivalent of incompetency rendering one totally incapable of giving informed consent to medical treatment. For example, when medication is administered as part of an aversive treatment program, as an experiment, in violation of firmly held religious views, or by a competent prisoner objecting to surgery, that treatment has been held by lower courts to be constitutionally prohibited. *Knecht* v. *Gillman,* 488 F.2d 1136 (8th Cir. 1973)(aversion therapy); *Mackey* v. *Procunier,* 477 F.2d 877 (9th Cir. 1973) (experimental drug); *Winters* v. *Miller,* 446 F.2d 65 (2d Cir. 1971) (religious objections); *In re Boyd* 403 A.2d 744 (D.C. 1979) (religious objections); *Runnels* v. *Rosendale,* 499 F.2d 733 (9th Cir. 1974) (prisoner objection to hemorrhoidectomy).[15]

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[15] Other treatments which have undergone statutory preclusion or strict judicial scrutiny include psychosurgery, *Kaimowitz* v. *Department of Mental Health,* no. 73-19434-A.W., 42 U.S.L.W. 2063 (Mich. Cir. Ct., July 10, 1973), and electroconvulsive therapy, *see, e.g., Wyatt* v. *Stickney,* 344 F.Supp. at 380. Psychiatric therapies which have drawn critical objection on the basis of lack of informed consent include inhalation therapy and addiction therapies. IV Report of the Task Panel of the President's Commission on Mental Health-Appendix 1431, 1435 (1980). Mental institutions also may not use drugs as punishment or for purposes of insuring a better life style of the patient. *Knecht* v. *Gillman,* 488 F.2d 1136 (8th Cir. 1973); *O'Connor* v. *Donaldson,* 422 U.S. 563 (1975).

The extent to which a state may treat using conventional and widely accepted antipsychotic drugs under either its police power or as *parens patriae* is unsettled. The collison of the goals of having a patient committed to the state (and its psychiatrists) for the purpose of providing treatment for an illness with the threat of the psychiatrist facing litigation if medically acceptable therapy is forced on an unwilling patient places psychiatrists in an untenable position. M. Ford, *The Psychiatrist's Double Bind: The Right to Refuse Medication,* 137 Am. J. Psychiatry 332 (1980). One risk of the present legally ambiguous situation is that psychiatrists will stop giving necessary medication in order to avoid potential personal involvement in litigation. *See* Roth, *supra,* at 355.

C. A Qualified Constitutional Proscription Attaches To The Forcible Antipsychotic Drug Medication Of An Involuntarily Committed Patient.

The majority of the federal courts which have examined the right of a committed mental patient to refuse antipsychotic drugs have determined that there is a qualified federal constitutional right to refuse medication.[16] *Rogers* v. *Okin,* 634 F.2d 650, 653-59 (1st. Cir. 1980); *Rennie* v. *Klein,* 426 F.Supp. 1131, 1145 (D.N.J. 1978); *Davis* v. *Hubbard,* 506 F.Supp. 915, 929-30 (N.D. Ohio 1980). *See also Scott* v. *Plante,* 532 F.2d 936, 946 (3d Cir. 1976); *Bell* v. *Wayne County General Hospital at Eloise,* 384 F.Supp. 1085, 1102 (E.D. Mich. 1974); Title V of the Mental Health Systems Act, 42 U.S.C.

[16] State courts examining their own mental commitment laws have been less inclined to interfere in a therapeutic regimen structured to respond to a patient's needs. *See Prince* v. *Sheppard,* 307 Minn. 250, 239 N.W.2d 905 (1976) (electroshock therapy); *see also Nason* v. *Superintendant of the Bridgewater State Hospital,* 353 Mass. 604 (1968); *Whitree* v. *State,* 290 N.Y.S.2d 486 (1968).

§9501(1)(D) (1981). *But see Rone* v. *Fireman*, 473 F.Supp. 92, 108 (N.D. Ohio 1979). The right has been founded on the constitutional right to privacy in *Rogers* and *Rennie* and on substantive due process in *Davis*. *Rogers* v. *Okin*, 634 F.2d at 653; *Rennie* v. *Klein*, 462 F.Supp. at 1144; *Davis* v. *Hubbard*, 506 F.Supp. at 929. A common law correlate of that right is found in the tort doctrine of informed consent. *See Rogers* v. *Okin*, 478 F.Supp. at 1366; *Scott* v. *Plante*, 532 F.2d at 946; *Rennie* v. *Klein*, 462 F.Supp. at 1144.

1. The doctrine of informed consent

Amicus agrees that the applicability of the modern tort doctrine of informed consent[17] to institutionalized psychiatric patients is a core issue in this case. The professed philosophical underpinning of informed consent is that espoused by John Stuart Mill in *On Liberty:* "The only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant . . ." J. S.

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[17] The law of informed consent in malpractice cases did not arouse significant legal attention until the 1960's. *See* Comment, *Informed Consent in Medical Malpractice*, 55 Cal L. Rev. 1396, 1399 (1967); *see also* W. Prosser, Law of Torts 165 (4th ed. 1971).

One area in which informed consent is recognized by physicians to be particularly applicable is in the area of research. The Food and Drug Administration recently published its final rules implementing standards of informed consent for research. *See* FDA, *Protection of Human Subjects; Informed Consent*, 46 Fed. Reg. 8942 (January 27, 1981). The ACNP has adopted its own ethical principles, which include informed consent for research on human subjects. American College of Neuropsychopharmacology, *A Statement of Principles of Ethical Conduct for Neuropharmacological Research in Human Subjects* (Principle 8), in Legal and Ethical Issues in Human Research and Treatment: Psychopharmacologic Considerations 12 (D. Gallant & R. Force ed. 1977).

Mill, On Liberty 11 (D. Spitz ed. 1975). Yet, even John Stuart Mill provided exceptions for those without the "full use of their reflecting faculty" and those that require being taken care of by others. *Id.* at 89, 95. *See* Lasagna, *supra* note 10 at 21. Justice Cardozo cautioned his formulation of the requirement for consent to surgery by noting that "Every human being of adult years and *sound mind* has the right to determine what shall be done with his own body. . . ." *Schloendorff* v. *Society of New York Hospitals,* 211 N.Y. 125, 105 N.E. 92, 93 (1914) (emphasis supplied).

Concerning the medical treatment of rational patients, the philosophy of a person being his own judge as to whether treatment is justified is a laudable goal. Essentially, it permits the layman to make a risk-benefit analysis of a medical activity, utilizing the expert advice of physicians. For psychiatric treatment, consent by the patient is certainly the preferred route. *O'Connor* v. *Donaldson,* 422 U.S. 563, 579 (1975) (Burger, C. J. concurring); D. Klein, *et al., supra,* at 28-34, 188.

For severely ill psychiatric patients, however, this model of the individual rationally balancing the risks and benefits of antipsychotic medication fails. As opposed to other fields of medicine, "[i]t is the nature of psychiatry to work with patients who suffer from impaired perceptions of themselves and the world. It is an impairment of the 'consenting organ' itself which is being treated."[18] A. Johnson and B. Eichelman, *Ethical Issues in Psychopharmacologic Treatment,* in Legal and Ethical Issues in Human Research and Treatment: Phar-

[18] Patients suffering from psychoses may refuse medication either because they do not recognize they are ill or because they believe they deserve a bad fate. Lasagna, *supra,* at 24; R. Shader, *Importance and Implications for Psychiatric Research and Practice of the Boston and Manteno State hospital Cases,* 16 Psychopharm Bull. 20, 21-22 (Oct. 1980).

macologic Considerations 145 (D. Gallant & R. Force ed. 1978).

Although informed consent serves as a guide to the determination of the liberty and privacy interests of the patient, it does not provide a complete answer to the issue of a committed patient's constitutional rights. Examining the extent of the right to refuse medical treatment requires a balancing of individual and state interests. *Cf. Wolff* v. *McDonnell*, 418 U.S. 539, 560 (1974); *Morrissey* v. *Brewer*, 408 U.S. 471, 481-90 (1972).

2. Balancing individual and state interests

The essence of the individual interest asserted is the right of privacy and the avoidance of further interference with the right to liberty of an involuntarily committed patient. In the short run, the experience of having medicine injected into the posterior is certainly not a pleasant event for a psychotic patient undergoing severe agitation, but it is not the type of bodily invasion which alone would necessarily amount to a threshold constitutional deprivation. Cf. *Schmerber* v. *California*, 384 U.S. 757 (1966); *Breithaupt* v. *Abram*, 352 U.S. 432 (1957). Other factors which bear on the interest of the individual include his religious beliefs, the possible side effects of the medicine, the consequences for the patient if the medicine is refused and the prognosis with treatment. *See, e.g., In the Matter of Guardianship of Richard Roe III*, Mass Adv. Sh. at 1003-1010.

The interests of the state involve protecting the public safety; providing for the efficient and common sense operation of the institution; and eradicating or lessening the extent of mental illness and the destructive effects it has on public safety, the family and on the individuals involv-

ed.[19] *See Rogers* v. *Okin*, 634 F.2d at 654-59. *See also In the Matter of Guardianship of Richard Roe III*, Mass Adv.Sh. at 1016-1018. Amicus submits that the treatment of the patient is an additional interest of the state.[20]

In balancing the interests of the individual and the state, it is clear that while an individual's rights inside a psychiatric facility should not be ignored, any "right to refuse treatment" is qualified by the need to protect the public safety. Therefore, in emergency situations, the administration of antipsychotic drugs is warranted to preclude violence by a patient against another patient or upon himself. *Rogers* v. *Okin*, 634 F.2d at 656; *Rennie* v. *Klein, 462 F.Supp. at 1145; See also Goss* v. *Lopez*, 419 U.S. 565, 582 (1975). When a patient is in a pivotal condition in which the absence of antipsychotic medication would possibly plunge him into rapid decline, then, in most circumstances, the patient should also be treated. *See Rogers* v. *Okin*, 634 F.2d at 659-660; *Rennie* v. *Klein*, 402 F. Supp at 1152-1154; R. Shader, *Importance and Implications for Psychiatric Research and Practice of the Boston and Manteno State Hospital*

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[19] One state interest unrecognized by the lower courts provides that restrictions upon the use of antipsychotic drugs of already proven therapeutic value should not be so severe as to discourage future research in the area. *Cf. San Antonio Independent School District* v. *Rodriquez*, 411 U.S. 1, 42-43 (1972).

[20] The treating physician is unlikely to segregate his patients into individuals commited under the police power and those committed under *parens patriae*. Amicus suggests that making treatment decisions pursuant to this distinction is unwarranted in light of the legislative determination to put dangerous individuals into treatment centers rather than jails. Individuals who are dangerous but who are not diagnosable as mentally ill obviously should not be administered antipsychotic medication.

Cases, in 16 Psychopharmacology Bulletin 20-21 (No. 4, October 1980).

Translating the constitutional right into practical terms, the major individual interest to be protected is the freedom of the individual from the irreversible side effects of a class of drugs used over a long period of time. *See Rennie* v. *Klein* 462 F.Supp. at 1154. Current medical evidence indicates that short-term use of antipsychotic medication is unlikely to lead to tardive dyskinesia. D. Klein, *et al., supra,* at 188; R. Shader & A.H. Jackson, *Approaches to Schizophrenia,* in Manual of Psychiatric Therapeutics 88. Therefore, the crucial aspect of the right requires periodic review of the treatment regimen undertaken by the state. In the event that tardive dyskinesia could be avoided with improvements in antipsychotic medication or treatment of the side effect, then any presumption against the long-term administration of antipsychotic medication in the treatment regimen would be seriously diminished.[21]

In summary, while there is a constitutional right relating to the nonemergency, involuntary administration of antipsychotic medicine, it is a qualified right. In many patient circumstances, the patient's asserted right is overcome by the need to receive proper treatment and by the state's interests. These include protecting the patient, other patients, and hospital staff from physical violence, precluding self-destructive behavior of a grave nature, and administering medically acceptable treatment.

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[21] For example, in the mid-70's, the drug clozapine was thought to be an effective antipsychotic which did not produce extrapyramidal side effects and which also possibly reversed the effect of tardive dyskinesia. Unfortunately, testing in Finland revealed a high frequency of agranulocytosis, a blood disorder, and it was removed from further testing. D. F. Klein *et al., supra,* at 117-118.

II. ALTHOUGH THE NORMAL SAFEGUARDS OF PROPER MEDICAL CARE PROTECT COMMITTED MENTAL PATIENTS, A DUE PROCESS HEARING IS REQUIRED PRIOR TO THE NON-EMERGENCY ADMINISTRATION OF ANTIPSYCHOTIC MEDICINE.

In the protection of the constitutional right to treatment initiation review and subsequent periodic review of the involuntarily administration of antipsychotic medicine, the due process procedure which should attach to the right must be oriented towards the specific interest to be protected and the medical nature of the threatened right. Lower court treatment of these interests has failed to fully consider particular protections which now operate to favor the interests of the patient.

A. Federal Drug Regulation, State Tort Law And The Ethical Tenets Of The Medical Profession Offer Protection Against The Improper Use Of Antipsychotic Medication.

Congress has established an elaborate regulatory mechanism for the approval of pharmaceutical drugs. *See* Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.* (1981). These statutory requirements ensure that a risk-benefit analysis will have already taken place prior to a drug ever reaching the state mental health physician. The drug regulatory system also imposes a duty upon drug manufacturers to disclose any reported negative effects of medication. *See* 21 U.S.C. §355(e); 21 C.F.R. §§310.300(b)(2), 310.301 (1980). In the exercise of its discretion, the Food and Drug Administration, being fully aware of the incidence of tardive dyskinesia, has not sought to remove antipsychotic drugs from distribution, although it would be empowered to do so if it determined on the basis of the clinical experience of

the drugs' use that they are unsafe or have not been shown to be safe. *See, e.g., Forsham* v. *Califano,* 422 F.Supp. 203 (D.D.C. 1977), *aff'd on other grounds,* 190 U.S. App. D.C. 231, 587 F.2d 1128 (1978).

Psychiatric patients are further protected from unsafe drugs through the private law actions of medical malpractice and product liability and through the ethical tenets of the medical profession. These state tort law causes of action provide remedies for any patients who receive medical care below the standard of care or who are sold unsafe drugs. The common law rights of action make constitutional protections less necessary. *Cf. Ingraham* v. *Wright,* 430 U.S. 651, 670 (1977). In addition, the Hippocratic Oath specifically addresses treatment regimen where a physician states, "I will prescribe regimen for the good of my patients according to my ability and my judgment and never do harm to anyone." Dorland's Illustrated Medical Dictionary 715 (25th ed. 1974). For the vast majority of treating psychiatrists, these common law and ethical proscriptions serve to guide their choice of treatment.

B. Due Process For The Protection Of The Rights Of An Involuntarily Committed Mental Patient Should Consist Predominantly Of Periodic Review By A Treatment Review Board.

Even though numerous protections exist to guard against the improper medication of involuntary patients, the long-term risk of error in treatment given against a person's will is sufficient to require that an impartial decision-maker determine whether the nonconsensual administration of antipsychotic medication is justified. The impartial decision-maker need not be a judge sitting in a county courthouse. This Court has previously tailored

due process in the mental health area to serve the interests of federalism and the particular nature of medical treatment. *See Parham* v. *J.R.*, 442 U.S. 584, 608 (1979); *Addington* v. *Texas*, 441 U.S. 418, 432 (1979). Even more than the commitment concerns involved in those cases, the decision as to proper medical treatment for mental patients involves judgments for which an adversarial courtroom setting and the formalized legal process is often inappropriate.

The decision concerning involuntary medication could occur either at the judicial commitment hearing or at a subsequent administrative hearing at the treatment facility. For the majority of patients, amicus suggests that the proper forum for this type of decision-making review would be a treatment review board.[22]

1. Treatment decisions at admission

For some patients, and where state law permits, the issue of the right to refuse treatment could be resolved by a judicial determination at the time of commitment. Initial medication decisions could be made for individuals whose prior record suggested an overriding need for antipsychotic drug treatment such as: (1) violent assertive patients with histories that indicate that they will be a threat to themselves, to other patients or to staff, and (2) psychotic patients who could be ex-

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[22] Amicus recognizes that this Court has refrained from outlining the precise means by which states must comply with due process requirements in mental health cases. *Parham* v. *J.R.*, 442 U.S. at 607; *Addington* v. *Texas*, 441 U.S. at 433. It has, however, made suggestions concerning appropriate procedures. *Parham* v. *J.R.*, 442 U.S. at 608; *Addington* v. *Texas*, 441 U.S. at 432. The treatment review board proposal is offered as a practical, comprehensive and legally acceptable alternative to either the lack of review or cumbersome guardianship proceedings of dubious utility.

pected to deteriorate irreversibly without drug treatment. In other initial commitment cases, a decision regarding the necessity for medication could be decision-making in a vacuum.

2. Subsequent objection and periodic review of medication

After a patient is committed to a mental institution, returning that patient to a regular trial court or a probate court prior to the administration of medication, even in a nonemergency, is not likely to be in the interest of either the patient, the institution, or the state. As observed in *Parham,* doctors attending hearings are not attending patients. *Parham* v. *J.R.*, 442 U.S. at 606.

A treatment review board composed of individuals from various professions, including law and medicine, and also public members is a preferable administrative alternative to judicial determination of involuntary medication claims. The board would provide expertise to the resolution of these claims provided that a psychiatric expert in psychopharmacology sits on the panel.

This treatment review board would be able to ascertain the objections of the patient to the initial administration of antipsychotic medication. It also would hear and record the claims of the treating staff concerning the need of the patient for antipsychotic medication and the need to protect other patients. The independant psychiatrist,[25] with candor and an expectation of legal

[25] Board-certified psychiatrists would be the preferred candidates for these positions, since 20% of the written examination administered by the American Board of Psychiatry and Neurology consists of "biological" questions. At least one-third of the approximately 33,000 psychiatrists in the U.S. are board-certified.

immunity, could advise the board concerning the current risks and benefits of drug therapy and could also assist in determining the inappropriate use of tranquilizing medications.[24] The board would then approve or disapprove a basic treatment regimen for the patient, balancing the delicate individual and state interests in a fair and unbiased manner. After a suitable period, the efficacy and the need for any medication would be reviewed, with a presumption arising over the long-term against unvaried involuntary medication. Such an administrative review would provide sufficient protection for the constitutional rights of the patient while ensuring that patients are not improperly confined without treat-

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Continuing medical education in psychopharmacology is offered under the auspices of the American Psychiatric Association and local medical societies. Participation in such courses should be considered a prerequisite to membership on a treatment review panel.

[24] An example of the effective use of outside review of medication decisions is found in the resolution of the involuntary medication issue in *Rone* v. *Fireman*, 473 F.Supp. at 107-110. Prior to 1977, the drug practices at Western Reserve Psychiatric Habilitation Center were generally not in accord with recognized professional standards. In response to a suit by three patients under 42 U.S.C. § 1983, the State of Ohio upgraded the staffing of the hospital, including the hiring of a psychologist with an expertise in psychopharmacology and conducted a review of medication practices at the hospital by an outside psychopharmacological expert. Corrective steps taken by the State convinced the District Court that concerns regarding the administration of psychotropic drugs had been met at the hospital and no remedial action was ordered. *Id.*, at 110. Beyond advisable administrative controls, however, treatment decisions, and the choice, as well as the review, of medication in individual cases require the advice and knowledge of a psychiatrist with an expertise in psychopharmacology.

ment, serving the procedural concerns enunciated by this Court in *O'Connor* v. *Donaldson*, 422 U.S. at 576, and *Parham* v. *J.R.*, 442 U.S. at 607. It would also avoid a further unwelcome intrusion onto crowded state court dockets with subject matter for which a state court might ". . . find itself wandering amid the mazes of therapeutics or boggling at the mysteries of the pharmacopoeia." *Granville* v. *Gregory*, 83 Mo. 123, 137 (1884).

C. An Incompetency Determination Is Neither Appropriate Nor Necessary.

Amicus contends that it is entirely inappropriate to force patients to be declared incompetent for all purposes (global incompetence) in order that a patient's objections to antipsychotic medication be overruled by an outside decision-maker. Psychiatrists have been the leaders in legal reform efforts designed to remove the additional stigma of incompetency from a temporary involuntary commitment adjudication. *See* Lasagna, *supra*, at 23; D.F. Klein, *Boston Hospital: An Update and Comment*, 23 A.P.A. Bulletin 3 (May-June 1981). The competency of a patient with a psychotic disorder to handle personal affairs can vary from day to day. A patient need not carry the more debilitating tag of global incompetence as a constitutional prerequisite to receiving temporary, necessary medical treatment, even on an involuntary basis.

These considerations, and others enumerated in this brief, suggest that in order to constitutionally address the conflicting interests of society, the medical profession and the committed patient objecting to the involuntary administration of antipsychotic medicine, the Constitution requires a due process hearing. In this

predominantly medical context, due process should take the form of review in the hospital setting by a treatment panel which has a psychiatrist with an expertise in psychopharmacology as a member of the panel.

CONCLUSION

For the foregoing reasons, the decision of the United States Court of Appeals for the First Circuit should be reversed and remanded for further consideration in light of the reasoning presented above.

Respectfully submitted,

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